

**RESPONSE UNDER 37 CFR § 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 1612**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : **Confirmation No. 2813**
Tetsuya SUZUKI : Attorney Docket No. 2005_1548A
Serial No. 10/554,205 : Group Art Unit 1612
Filed December 12, 2005 : Examiner Darryl C. Sutton

COMPOSITION FOR ORAL ADMINISTRATION
CONTAINING ALKYLENE DIOXYBENZENE
DERIVATIVE : **Mail Stop: AF**

REQUEST FOR RECONSIDERATION AFTER FINAL REJECTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**THE COMMISSIONER IS AUTHORIZED
TO CHARGE ANY DEFICIENCY IN THE
FEES FOR THIS PAPER TO DEPOSIT
ACCOUNT NO. 23-0975**

Sir:

Responsive to the final Office Action of March 11, 2009, Applicant submits the following remarks in support of the patentability of the presently claimed invention over the disclosures of the references relied upon by the Examiner in rejecting the claims. Further and favorable reconsideration is respectfully requested in view of these remarks.

Consideration After Final Rejection

Although this response is presented after final rejection, the Examiner is respectfully requested to enter and consider the remarks, as they demonstrate that the application is in condition for allowance.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 6 is rejected under 35 U.S.C. § 112, second paragraph, as having uncertain claim scope due to the presence of trademarks or trade names in the claim. Specifically, the Examiner states that claim 6 contains the trademarks/trade names methacrylic acid copolymer “L”, “S” and

“LD”. The Examiner states that the claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product.

This rejection is respectfully traversed.

Applicant respectfully clarifies that claim 6 does not contain trademarks or trade names. On the contrary, the affixes “L”, “S” or “LD” for methacrylic acid copolymers are commonly used to define sub-types of methacrylic acid copolymer. None of these terms are trademark or trade name, and thus, their presence in claim 6 does not render the claim indefinite.

Accordingly, it is respectfully requested that the above-rejection be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

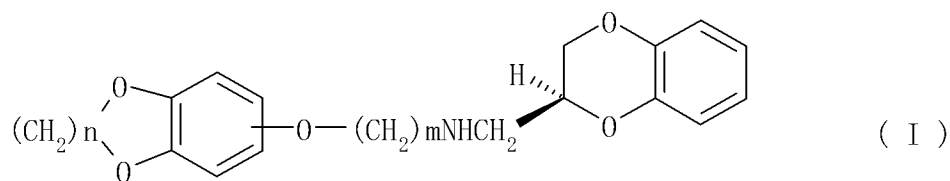
Claims 6, 9-12, 21 and 22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Abe et al. (U.S. Publication 2002/0091152), and further in view of Remington (1995), and further in view of Mendes et al. (U.S. 6,468,560).

Claims 7 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Abe et al., Remington and Mendes et al., and further in view of Nakamichi et al (U.S. 5,700,410).

These rejections are respectfully traversed for the reasons set forth below.

Applicant's claim 6 recites:

“A composition for oral administration comprising an enteric film-coated granule, wherein the granule comprises an alkylendioxybenzene derivative represented by the general formula (I):



wherein m represents an integer of 2 to 5, and n represents an integer of 1 to 3, or an acid addition salt thereof,

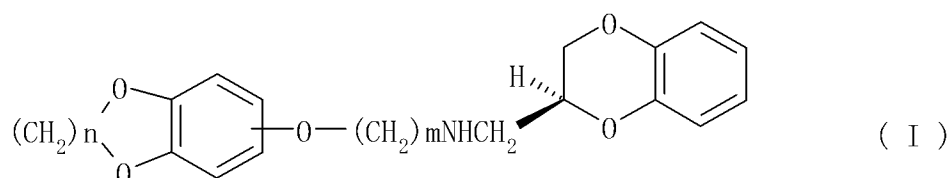
which is dispersed in a matrix comprising one or more waxes, and

wherein the enteric film coating comprises a copolymer selected from the group consisting of methacrylic acid copolymer LD, methacrylic acid copolymer L, methacrylic acid copolymer S,

and combinations thereof.”

Applicant’s claim 10 recites:

“A process for preparing a composition for oral administration, comprising kneading an alkylendioxybenzene derivative represented by the general formula (I):



wherein m represents an integer of 2 to 5, and n represents an integer of 1 to 3,
or an acid addition salt thereof,

which is dispersed in a matrix comprising one or more waxes, to obtain a granule, and
coating the granule with an enteric film comprising a copolymer selected from the group
consisting of methacrylic acid copolymer LD, methacrylic acid copolymer L, methacrylic acid
copolymer S, and combinations thereof.”

As admitted by the Examiner (first full paragraph on page 4 of the Office Action), Abe et al. fail to teach a matrix comprised of wax. Additionally, as also admitted by the Examiner, Abe et al. fail to teach the active agent (a compound according to formula (I)) dispersed in a wax matrix (to obtain a granule), where the granule is coated with an enteric coating film comprising a copolymer selected from the group consisting of methacrylic acid copolymer LD, L, S and combinations thereof.

The Examiner takes the position that Remington and Mendes et al. cure these admitted deficiencies of Abe et al.

However, Applicants respectfully disagree. Remington fails to teach a matrix comprised of wax, coated with an enteric coating film comprising a copolymer selected from the group consisting of methacrylic acid copolymer LD, L, S and combinations thereof. None of the compositions taught by Remington comprise a wax matrix coated with an enteric coating film comprising a specific methacrylic acid copolymer. On the contrary, the Examiner has relied upon two different portions of the general Remington reference to assert that both a wax matrix, and an

enteric coating would be obvious. The Examiner appears to take the position that these (wax matrix and enteric coating) would be obvious together, although the Examiner has not provided a motivation for this position. Furthermore, Remington fails to teach that the active agent is a compound of formula (I).

Although Mendes et al. disclose that an enteric coating layer can be applied to the insulating layer, Mendes et al. do not teach the enteric coating layer comprising methacrylic acid copolymer LD, L, S and combinations thereof, as required by Applicant's claims. Further, Mendes et al. fail to teach the active agent (a compound of Formula (I)) in a wax matrix, coated with an enteric coating film.

Thus, the teachings of Remington and Mendes, taken alone or in combination, fail to remedy the deficiencies of Abe et al.

Furthermore, the Nakamichi reference is only relied upon to teach mixing ratios of wax. Thus, Nakamichi et al. clearly fail to remedy the deficiencies of the above-discussed combination of references.

For the reasons set forth above, the subject matter of Applicant's claims is clearly patentable over the cited combinations of references. Accordingly, Applicant respectfully requests that the rejections be withdrawn.

Conclusion

Therefore, in view of the foregoing remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this response, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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